William Laboratories, Inc.

STANDARD OPERATING PROCEDURE

REF: QCP/0200-4
ISSUE: 1
REV: 0
DATE: 08/21/06
APP'D: .....

VALIDATION PROTOCOL

- Safe-T-Vue 10, Product No. 7201
- Safe-T-Vue 8, Product No. 7208

Process to be validated – Temperature Measurement of Color Change in Safe-T-Vue 10, Product Number 7201 (STV 10), and Safe-T-Vue 8, Product Number 7208, (STV 8).

References: William Laboratories, Inc. Product Sheet SAL/0100-1, Rev 0, 8/29/06. *American Association of Blood Banks* **Standards for Blood Banks and Transfusion Services**, Reissue of Blood and Components. Package insert "*Handling/Use Instructions/Frequently Asked Questions (FAQs and Color change Interpretation Information* ". Lot and Product specific Quality Assurance Documents.

Purpose of Validation – To assure a consistent method of measuring and interpreting color-related temperature change in STV 8 and STV 10 when used as a temperature monitoring indicator on blood products contained in flexible plastic bags where such products have an upper limit temperature of 8° C for STV 8 and 10° C for STV 10.

Installation Qualification (IQ)

1. Process Description – The measurement and interpretation of the temperature-related color change for STV 8 and STV 10 is a simple procedure consisting of assuring starting temperatures, the use of temperature measuring instruments, and the correct physical handling of STV 8 and STV 10.
2. Equipment Design/Description
   a. A refrigerator with temperature control between 1° and 6° C;
   b. A simulated blood bag consisting of a common, flexible plastic blood bag filled with the appropriate volume of glycerol-water mixture (approx. 10% by wt. glycerol) to simulate blood mass and volume;
   c. An electronic thermometer, such as a "DigiSense" thermister electronic thermometer with an immersion probe, or similar temperature measuring instrument that can be calibrated;
      i. The temperature measuring probe is inserted through the appropriate bag opening into the simulated blood bag positioned so that it is in the approximate center of the liquid in the bag;
      ii. The bag with probe in place ready for reading is to lie flat with the probe so positioned that it assures temperature measurement of the 'core' temperature of the liquid mass.
3. Sample Preparation – [Refer to package insert "*CHANGE THIS NAME*".]
   a. STV to be tested must be stored in refrigerator at 1° to 6° C for at least 24 hours prior to test;
   b. Simulated blood bags used for this test must be stored in a refrigerator between 1 and 6° C;

c. Remove simulated blood bag with temperature measurement probe from refrigerator and place on lab bench;
   i. Connect probe to electronic thermometer.
d. Remove one or more STV from refrigerator taking great care to handle STV by the round, colored end;
   i. Peel off the "Remove" label to expose the adhesive and attach STV directly to the blood bag where there is the greatest volume of liquid and immediately above the measurement probe;
   ii. Stabilize STV against bag with fingertips and peel off the top foil lid to expose the red and white rounds;
   iii. **Activate** by folding the white round into the red round, then press firmly together by pressing only on the colored, round label.

4. Observation parameters for determining the temperature of color change.
   NOTE: The temperature differential between ambient conditions and the environment of a validated cooler is significant; frequent massage of the simulated blood bag is necessary to maintain temperature at the bag surface to be very close to the core temperature of the bag and assure accurate color-temperature obsevations.
   a. The color change in the round white area is from white to a rose-red or red color.
   b. The color change process from an all-white to and all-red color typically takes place over about 1° C.
   c. The color change process may be described as progressive by observing in sequence:
      i. Small, rose or red spots around the edges of the white area and/or within the white area;
      ii. Areas of rose or red spots coalescing into areas of rose-red to red color;
      iii. The entire white area is rose-red to red indicating attainment of **8° C for STV 8** and **10° C for STV 10**; a positive control is helpful for color comparison.
   d. Repeat process with one or more STV temperature indicators until satisfied that the process will consistently produce results meeting the specifications and quality characteristics of the product.

Critical Process Variables

1. Refrigerator temperature range;
2. Calibration of temperature-measuring instruments
3. Handling of samples

Conditions to be Monitored

1. Storage of STV 8 and STV 10 in refrigerator so that 'warm air wash' from normal opening and closing of the door does not warm the indicators to above 10° C prior to use.
2. Training to assure consistent handling and application of STV 8 and STV 10.

QA Manager Review Edward Shaffer Date Aug 21, 2006